

REMARKS

Claims 1-59 were pending in this application. Claims 1-30, 32, 33, and 43-59 are canceled. Claims 31 and 34-42 are amended. Claims 60-63 are newly presented. After entry of this amendment, claims 31, 34-42, and 60-63 will be pending in this application. Applicants submit that these amendments add no new matter.

Amendments to the Specification

Applicants have amended paragraph 68 of the specification to reference a patent application by application serial number that was previously referred to by title and attorney docket number. Paragraph 68 was also amended to correct a grammatical error objected to by the Examiner. Applicants submit that these amendments add no new matter.

Amendments to the Claims

Independent claim 31 is amended to recite a method for stabilizing a tissue for implanting an occlusion device in a patient. The method comprises the steps of introducing into a heart of a patient a delivery member having at least a first flexible member, the first flexible member having a first end portion and a second free end portion; introducing the second free end portion of the first flexible member through a patent foramen ovale; contacting the second free end portion with a left atrial side of a septum primum; puncturing a hole through the septum primum; withdrawing the second free end portion of the flexible member from the left atrial side; and introducing an occlusion device for occluding a patent foramen ovale through the hole in the septum primum. Support for this amendment can be found in the application as originally filed, for example, at least at lines 3-7 of paragraph 52, at lines 3-5 of paragraph 67, at lines 7-12 of paragraph 71, at lines 4-9 and 15-17 of paragraph 74, and at lines 1-3 and 8-18 of paragraph 79.

Independent claim 37 is amended to recite a method for stabilizing a tissue for implanting an occlusion device in a patient. The method comprises the steps of introducing into the heart of a patient a delivery member for delivering a plurality of hexagonally shaped flexible members; introducing said hexagonally shaped flexible members through a patent foramen ovale; placing at least one of said hexagonally shaped flexible members on a left atrial side of a septum primum; and withdrawing the at least one hexagonally shaped flexible member from the left

atrial side. Support for this amendment can be found in the application as originally filed, for example, at least at lines 5-8 of paragraph 64, at lines 7-10 of paragraph 71, at lines at lines 8-18 of paragraph 79, and at lines 6-8 of paragraph 82.

Claims 35 and 41 are amended to recite the step of introducing an apparatus for joining tissue. Support for this amendment can be found in the application as originally filed, for example, at lines 7-9 of paragraph 68.

Claims 38 is amended to recite forming a hole in said septum primum. Support for this amendment can be found in the application as originally filed, for example, at lines 1-6 of paragraph 66, at lines 1-5 of paragraph 67, and at lines 15-17 of paragraph 74.

Claim 39 is amended to recite providing an occlusion device for occluding said patent foramen ovale through the hole in the septum primum. Support for this amendment can be found in the application as originally filed, for example, at lines 1-6 of paragraph 66, at lines 1-5 of paragraph 67, at lines 15-17 of paragraph 74, and at lines 12-19 of paragraph 79.

Support for new claims 60-63 can be in the application as originally filed, for example, at lines 1-3 of paragraph 59, at lines 1-4 of paragraph 69, at lines 1-4 and 7-10 of paragraph 71, and at lines 4-11 of paragraph 74.

Claims 34 and 35 are amended to recite appropriate dependencies.

Claims 36 and 42 are amended for antecedent basis purposes.

Claims 34-36, and 40-42 are amended to correct an error in punctuation.

Objection to the Specification

The Office action objected to the specification because of a grammatical error at page 17, line 11. The Office action suggests that the phrase “an” should be inserted in the phrase “In other embodiment.” Applicants have amended the specification accordingly. Therefore, Applicants respectfully request that the object be reconsidered and withdrawn.

Claim Rejections under 35 U.S.C. § 102

Claims 31-34 and 37-40 stand rejected under 35 U.S.C. § 102(a) as being anticipated by U.S. Published Patent Application No. 2003/0208232 by Blaeser *et al.* (“Blaeser”). Applicants traverse the rejection to the extent it is maintained over the claims as amended.

Claims 32-33 are canceled. Therefore, Applicants respectfully request that the rejection of claims 32-33 be withdrawn.

It is well known law that in order for a claim to be anticipated, each and every element set forth in the claim must be found in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053.

Applicants submit that Blaeser is an improper reference under 35 U.S.C. 102(b) at least because Blaeser does not teach introducing into the heart of a patient a delivery member having at least a first flexible member, the first flexible member having a first end portion and a second free end portion, introducing the second free end portion through a patent foramen ovale, and contacting the second free end portion with a left atrial side of a septum primum, and withdrawing the second free end portion of the flexible member from the left atrial side of the septum primum.

Blaeser teaches devices and methods for sealing a passageway formed by a patent foramen ovale (abstract). In one embodiment, Blaeser teaches a delivery device. The delivery device is positioned with the patent foramen ovale. The delivery device never extends beyond the patent foramen ovale into the left atrium. In contrast, Applicants claimed invention requires that a second free end portion of a flexible member contact a left atrial side of a septum primum.

In another embodiment, Blaeser teaches using a suture and anchor assembly to close the patent foramen ovale by passing the suture assembly from the right atrial side of the septum secundum through to the left atrial side of the septum primum. Neither the suture device nor its delivery assembly is introduced through the patent foramen ovale into the left atrium. In contrast, Applicants claimed invention requires that a second free end portion of a flexible member is introduced through the patent foramen ovale and contacts the left atrial side of the septum primum.

Applicants submit that Blaeser cannot anticipate independent claim 31 or claim 34 depending therefrom at least because Blaeser is silent as to a second free end portion of a flexible member being introduced through a patent foramen ovale, contacting the second free end portion of the flexible member with the left atrial side of the septum primum and withdrawing the second free end portion of the flexible member from the left atrial side of the septum primum.

Applicants therefore respectfully request that the rejection of independent claim 31, and claim 34 depending therefrom in view of Blaeser be reconsidered and withdrawn.

Independent claim 37 recites, *inter alia*, introducing into the heart of a patient a delivery member for delivering a plurality of hexagonally shaped flexible members and introducing the hexagonally shaped flexible members through a patent foramen ovale.

In contrast to Applicants' claimed invention, Blaeser does not teach hexagonally shaped flexible members. For this reason, Applicants submit that Blaeser cannot anticipate independent claim 37 and claims 38-40 depending therefrom. Applicants therefore respectfully request that the rejection of claims 37-40 in view of Blaeser be reconsidered and withdrawn.

Claims 31, 35-36, 37, and 41-42 stand rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,749,895 to Sawyer *et al.* (Sawyer). Applicants traverse the rejection to the extent it is maintained over the claims as amended.

Each of independent claims 31 and 37 are directed to a method for stabilizing a tissue for implanting an occlusion device in a patient.

Claim 31 recites introducing into the heart of a patient a delivery member having at least a first flexible member, the flexible member having a first end portion and a second free end portion. The second free end portion is introduced through a patent foramen ovale and contacts the left atrial side of the septum primum.

Claim 37 recites introducing into the heart of a patient a delivery member for delivering a plurality of hexagonally shaped flexible members. The hexagonally shaped flexible members are introduced through a patent foramen ovale and at least one of the hexagonally shaped flexible members is placed on the left atrial side of the septum primum.

Sawyer teaches using a patch to join tissues. The patch is contacted with the tissues to be joined and energy is supplied to form a mechanical bond (col. 2, lines 50-55). For example, Sawyer teaches resecting portions of a bowel with a patch (col. 9, lines 49-61) or welding a patch to heart muscle (col. 10, lines 34-65).

In contrast to Applicants' claimed invention, Sawyer is silent as to any method involving the patent foramen ovale, let alone a method including introducing a second free end portion of a flexible member through a patent foramen ovale and contacting the second free end portion with the left atrial side of the septum primum.

Sawyer is also silent as to at least one hexagonally shaped flexible member being introduced through a patent foramen ovale and placing at least one of the hexagonally shaped flexible members on left atrial side of the septum primum. In fact Sawyer does not teach hexagonally shaped flexible members.

For all of these reasons, Applicants respectfully submit that Sawyer is an improper reference under 35 U.S.C. § 102(a). Accordingly, Applicants respectfully request that the rejection of independent claim 31 and claims 35 and 36 depending therefrom, and independent claim 37 and claims 41-42 depending therefrom be reconsidered and withdrawn.

CONCLUSION

Applicants submit that the currently pending claims are in condition for allowance. The Examiner is invited to telephone the undersigned attorney to discuss and outstanding issues.

Respectfully submitted,



Karen A. Schouten
Attorney for the Applicants
Kirkpatrick & Lockhart Nicholson
Graham LLP
State Street Financial Center
One Lincoln Street
Boston, Massachusetts 02111-2950

Date: November 1, 2006
Reg. No. 58,343

Tel. No.: (617) 261-3216
Fax No.: (617) 261-3175